#### AO 120 (Rev. 3/04)

TO:

# Mail Stop 8 Director of the U.S. Patent and Trademark Office P.O. Box 1450 Alexandria, VA 22313-1450

#### REPORT ON THE FILING OR DETERMINATION OF AN ACTION REGARDING A PATENT OR TRADEMARK

		IRIDENTIAL					
In compliar	nce with 35 U.S.C. § 290 and/or l	15 U.S.C. §	1116 you are hereby advised that a court action has been				
filed in the U.S. I	District Court for the District of I	Maryland o	the following				
OOCKET NO.	DATE FILED	U.S. DI	STRICT COURT FOR THE DISTRICT OF MARYLAND				
JFM-09-3464	12/28/09		101 W. Lombard Street, Baltimore, MD 21201				
LAINTIFF Medicis Pharmaceutical Cor	moration		DEFENDANT Bart Laboratories, Inc. et al				
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PATENT OR TRADEMARK NO.  1 2 3 4 5 In the abo DECISION/JUDGMENT	DATE OF PATENT OR TRADEMARK  ove-entitled case, the following de	beision has	HOLDER OF PATENT OR TRADEMARK  Deen rendered or judgment issued:				

- 29. Teva and Barr have infringed the '838 patent under 35 U.S.C. § 271(e)(2)(A) by virtue of their submission of the Barr ANDA Supplement to the FDA for generic SOLODYN™ minocycline HCl extended release tablets that are covered by one or more of the following claims of the '838 patent: claims 3, 4, 12, and 13.
- 30. Teva is jointly and severally liable for any infringement of one or more of claims 3, 4, 12, and 13 of the '838 patent. Teva's participation in, contribution to, aiding, abetting, and/or inducement of the submission of the Barr ANDA Supplement and its § 505(j)(2)(A)(vii)(IV) allegations to the FDA constitutes infringement of one or more of claims 3, 4, 12, and 13 of the '838 patent under 35 U.S.C. § 271(e)(2)(A).
- 31. The commercial manufacture, use, sale, offer to sell, importation or distribution of products under the Barr ANDA Supplement would infringe one or more of claims 3, 4, 12, and 13 of the '838 patent.
- 32. Medicis is entitled to an order requiring that Barr amend its Paragraph IV certification to a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(III) ("Paragraph III certification") as provided in 21 C.F.R. § 314.94(a)(12)(viii)(A).
- 33. Medicis is entitled to the relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of any FDA approval of the Barr ANDA Supplement be a date that is not earlier than the expiration of the '838 patent, or any later period of exclusivity for the '838 patent to which Medicis becomes entitled.
- 34. Medicis will be irreparably harmed if Teva and Barr are not enjoined from infringing or actively inducing or contributing to infringement of one or more of claims 3, 4, 12, and 13 of the '838 patent. Pursuant to 35 U.S.C. § 283, Medicis is entitled to a permanent injunction against further infringement. Medicis does not have an adequate remedy at law.

35. To the extent Teva and/or Barr commercialize their product, Medicis will also be entitled to damages under 35 U.S.C. § 284

#### PRAYER FOR RELIEF

WHEREFORE, Medicis respectfully requests that this Court enter judgment in its favor against Defendants and grant the following relief:

- A. an adjudication that Defendants have infringed one or more of the following claims of the '838 patent: claims 3, 4, 12, and 13, under 35 U.S.C. § 271(e)(2)(A), by submitting to the FDA the Barr ANDA Supplement to obtain approval for the commercial manufacture, use, offer for sale, sale, or distribution in and/or importation into the United States of generic SOLODYN<sup>TM</sup> minocycline HCl extended release tablets for the treatment of acne before the expiration of the '838 patent;
- B. an order requiring that Defendants amend their respective Paragraph IV certifications to Paragraph III certifications as provided in 21 C.F.R. § 314.94(a)(12)(viii)(A);
- C. an order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any FDA approval of the Barr ANDA Supplement for generic SOLODYN™ minocycline HCl extended release tablets be a date that is not earlier than the date of the expiration of the '838 patent or any later period of exclusivity to which Medicis is or may become entitled;
- D. a permanent injunction enjoining Defendants, their officers, agents, servants, employees, attorneys, and those persons in active concert or participation with any of them, from infringing the '838 patent, including the manufacture, use, offer to sell, sale, importation or distribution of any current or future versions of the product described in the Barr ANDA Supplement;

- E. an order enjoining Defendants, their officers, agents, servants, employees, attorneys, and those persons in active concert or participation with any of them, from infringing the '838 patent, including the manufacture, use, offer to sell, sale, importation or distribution of any current or future versions of the product described in the Barr ANDA Supplement while the litigation is pending;
- F. a judgment declaring that the manufacture, use, sale, offer to sell, importation or distribution of the products described in the Barr ANDA Supplement would constitute infringement of one or more of claims 3, 4, 12, and 13 of the '838 patent, or inducing or contributing to such conduct, by Defendants pursuant to 35 U.S.C. § 271 (a), (b) and/or (c);
  - G. a judgment declaring this to be an exceptional case;
- H. an assessment of pre-judgment and post-judgment interest and costs against Defendants, together with an award of such interest and costs, in accordance with 35 U.S.C. § 284; and
  - I. such other and further relief as this Court may deem just and proper.

Respectfully submitted.

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December 28, 2009

### CIVIL COVER SHEET

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. (SEE INSTRUCTIONS ON THE REVERSE OF THE FORM.)

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I. (a) PLAINTIFFS				DEFENDANTS			
Medicis Pharmaceutical Corporation				Barr Laboratories, Inc. & Teva Pharmaceuticals USA, Inc.			
(b) County of Residence of First Listed Plaintiff Maricopa County, AZ  (EXCEPT IN U.S. PLAINTIFF CASES)				Ounty of Residence of First Listed Defendant Bergen County, NJ  (IN U.S. PLAINTIFF CASES ONLY)  NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE LAND INVOLVED.			
					HYOLFED.		
(c) Attorney's (Firm Name, Address, and Telephone Number)				Attorneys (If Known) Thomas J. Meloro, Wilkie Farr & Gallagher LLP, 787 7th Ave.,			
Herbert Better & A. Pau Pratt St., Suite 2440, Ba					o, Wilkie Farr & Gall 1019. (212) 728-8241		
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#### IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF MARYLAND Northern Division

MEDICIS PHARMACEUTICAL CORPORATION, 7720 North Dobson Road Scottsdale, Arizona 85256

Plaintiff,

v.

CIVIL ACTION NO.

BARR LABORATORIES, INC., 400 Chestnut Ridge Road, Woodcliff Lake, NJ 07677

> Serve: Nicholas Tantillo 400 Chestnut Ridge Road, Woodcliff Lake, NJ 07677

OR

Scrve: Thomas J. Meloro Willkie Farr & Gallagher LLP 787 Seventh Avenue New York, NY 10019

And

TEVA PHARMACEUTICALS USA INC., 1090 Horsham Road, North Wales, Pennsylvania 19454

> Serve: Nicholas Tantillo 400 Chestnut Ridge Road, Woodcliff Lake, NJ 07677

OR

Thomas J. Meloro Willkie Farr & Gallagher LLP 787 Seventh Avenue New York, NY 10019

Defendants.

#### COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Medicis Pharmaceutical Corporation ("Medicis") for its Complaint against Defendants Teva Pharmaceuticals USA, Inc. ("Teva") and Barr Laboratories, Inc. ("Barr") (collectively, the "Defendants") alleges as follows:

#### I. THE PARTIES

- 1. Medicis is a Delaware corporation with its principal place of business at 7720 North Dobson Road, Scottsdale, Arizona 85256. Medicis is a leading independent specialty pharmaceutical company in the United States focusing on the treatment of dermatological conditions. Medicis's products have earned wide acceptance by both physicians and patients, including Medicis's SOLODYN<sup>TM</sup> extended release tablets for acne treatment.
- 2. Defendant Teva is a corporation organized and existing under the laws of the State of Delaware, with a principal place of business at 1090 Horsham Road, North Wales, Pennsylvania 19454. Teva is in the business of manufacturing, marketing, distributing, and selling, in the State of Maryland and throughout the United States, pharmaceutical drugs, including generic pharmaceutical drugs, manufactured by Barr and other corporate subsidiaries.
- 3. Defendant Barr is a corporation organized and existing under the laws of the State of Delaware, with a principal place of business at 400 Chestnut Ridge Road, Woodcliff Lake, New Jersey 07677, and is wholly-owned by Teva. Barr is in the business of manufacturing, marketing, distributing, and selling, in the State of Maryland and throughout the United States, pharmaceutical drugs, including generic pharmaceutical drugs.
- 4. On information and belief, Teva and Barr collaborate to manufacture, market, distribute, and sell pharmaceutical products, including generic pharmaceutical drugs

manufactured and sold pursuant to approved abbreviated new drug applications, in the State of Maryland and the United States.

#### II. NATURE OF THE ACTION

- 5. This is an action arising under the patent laws of the United States (Title 35, United States Code, § 100, et seq.) based upon Defendants' infringement of one or more of claims 3, 4, 12, and 13 of Medicis's U.S. Patent No. 5,908,838, entitled "METHOD FOR THE TREATMENT OF ACNE" ("the '838 patent"), relating generally to the field of acne treatment.
- 6. Barr, by and with Teva, filed Abbreviated New Drug Application No. 65-485 (the "Barr ANDA") under § 505(j) of the Federal Food, Drug, and Cosmetic Act (the "FFDCA"), to obtain approval to commercially manufacture and sell a generic version of SOLODYN<sup>TM</sup> minocycline HCl extended release tablets in its 45 milligrams ("mg"), 90mg, and 135mg strengths, for the treatment of acne.
- ANDA (the "Barr ANDA Supplement") under § 505(j) of the FFDCA, to obtain approval to commercially manufacture and sell a generic version of SOLODYN<sup>TM</sup> minocycline HCl extended release tablets in its 65mg and 115mg strengths, for the treatment of acne. Barr and Teva have infringed one or more of claims 3, 4, 12, and 13 of the '838 patent under 35 U.S.C. § 271(e)(2)(A) by virtue of their filing of the Barr ANDA Supplement with a Paragraph IV certification and seeking U.S. Food and Drug Administration ("FDA") approval of the Barr ANDA Supplement prior to the expiration of the '838 patent.

#### III. JURISDICTION AND VENUE

8. This Court has subject matter jurisdiction over Medicis's patent infringement claims under 28 U.S.C. §§ 1331 and 1338(a).

- 9. This Court has personal jurisdiction over Teva for a variety of reasons. First, Teva has previously consented to this Court's jurisdiction and taken advantage of the rights and protections provided by this Court. Second, Teva does substantial business, derives substantial revenue, and engages in persistent conduct in Maryland. Third, the infringement claims alleged in this action arise partially out of Teva's actions in Maryland.
- 10. Teva has previously consented to this Court's jurisdiction and availed itself of this State's protections. Indeed, Teva has repeatedly itself filed suit or intervened in pending suits in this District. See Teva Pharm. Indus. Ltd. v. Lupin Ltd., Civil Action No. 07-cv-00121-JFM (D. Md.); Teva Pharm. Indus. Ltd. v. Hetero Drugs Ltd., Civil Action No. 07-cv-00122-AW (D. Md.); Biovail Corp. v. U.S. Food and Drug Admin., Civil Action No. 06-cv-03355-RWT (D. Md.).
- On information and belief, Teva does substantial business in Maryland, derives substantial revenue from Maryland, and engages in other persistent courses of conduct in Maryland. Pursuant to the Maryland Long Arm statute, which is co-extensive with the limits of due process, Maryland can exercise personal jurisdiction over persons who "directly or by an agent . . . [c]ause[] tortious injury . . . if he regularly does or solicits business, engages in any other persistent course of conduct in the State or derives substantial revenue from goods, food, services, or manufactured products used or consumed in the State." Md. Code Ann., Cts. & Jud. Proc. § 6-103(b)(4).
- 12. On information and belief, Teva regularly does significant business in Maryland, through it sales to Maryland residents, and by and through Barr and other corporate subsidiaries. For the same reasons, Teva also derives substantial revenue from its business in Maryland. Moreover, Teva has recently made substantial business investments in Maryland, and

owns substantial assets in Maryland. For example, in 2008, Teva acquired CoGenesys, Inc., based at 9410 Key West Avenue, Rockville, Maryland 20850. At the time of the CoGenesys acquisition, Teva's President and CEO, William S. Marth, stated that "[Maryland] is the perfect place to grow the Teva Biopharmaceuticals USA business as Maryland is truly the home of medical technology innovation." In conjunction with the CoGenesys acquisition, Teva became the owner of CoGenesys's "48,000 square foot state-of-the-art facility, located in Rockville, Maryland." Finally, Teva engages in a persistent course of conduct in Maryland by regularly filing ANDAs with the FDA in Maryland, regularly making sales in Maryland, and through its involvement with CoGenesys, Inc. and other corporate subsidiaries. These continuous and systematic contacts, including but not limited to those described above and below, are more than sufficient for this Court to exercise general personal jurisdiction over Teva.

- This Court has personal jurisdiction over Barr for a variety of reasons. 13. First, Barr has previously consented to this Court's jurisdiction and taken advantage of the rights and protections provided by this Court. Second, Barr does substantial business, derives substantial revenue, and engages in persistent conduct in Maryland, with Teva as well as through sales to Maryland residents. Third, the infringement claims alleged in this action arise partially out of Barr's actions in Maryland.
- Barr has previously consented to this Court's jurisdiction and availed itself 14. of this State's protections by filing suit in this District. See Barr Labs., Inc. v. Am. Therapeutic, Inc., Civil Action No. 90-cv-01575-JRH (D. Md.); Barr Labs., Inc., v. Quantum Pharm., Inc., Civil Action No. 90-cv-03003-JRH (D. Md.).

<sup>&</sup>lt;sup>1</sup> Available at http://www.gov.state.md.us/pressreleases/080528.asp.
<sup>2</sup> Available at http://www.tevapharm.com/pr/2008/pr\_720.asp.

- derives substantial revenue from Maryland, and engages in other persistent courses of conduct in Maryland. Pursuant to the Maryland Long Arm statute, which is co-extensive with the limits of due process, Maryland can exercise personal jurisdiction over persons who "directly or by an agent . . . [c]ause[] tortious injury . . . if he regularly does or solicits business, engages in any other persistent course of conduct in the State or derives substantial revenue from goods, food, services, or manufactured products used or consumed in the State." Md. Code Ann., Cts. & Jud. Proc. § 6-103(b)(4). On information and belief, Barr regularly does significant business in Maryland through it sales to Maryland residents. For the same reason, Barr also derives substantial revenue from its business in Maryland. Finally, Barr engages in a persistent course of conduct in Maryland by regularly filing ANDAs with the FDA in Maryland. These continuous and systematic contacts, including but not limited to those described above and below, are more than sufficient for this Court to exercise general personal jurisdiction over Barr.
- 16. On information and belief, the claims in this action partially arise out of acts committed by Teva and Barr in Maryland. Pursuant to the Maryland Long Arm Statute, Maryland can exercise personal jurisdiction over persons who "directly or by an agent . . . [c]ause[] tortious injury in the State by an act or omission in the State." Md. Code Ann., Cts. & Jud. Proc. § 6-103(b)(3). On information and belief, Teva and Barr will, following any FDA approval of the Barr ANDA Supplement, sell the generic product that is the subject of the infringement claims in this action in the State of Maryland and throughout the United States, causing tortious injury to Medicis. Additionally, Teva and Barr participated in Maryland in the submission of the Barr ANDA Supplement, also causing tortious injury to Medicis. The

foregoing constitute acts in Maryland that directly give rise to Medicis's present claims of patent infringement.

- 17. Finally and alternatively, to the extent that Teva's acquisition of Barr in December 2008 constituted a full and complete merger of the two companies and rendered Barr a mere division or business unit of Teva, the factual allegations about Barr contained within this Complaint apply to Teva, and Teva's Maryland contacts should be imputed to Barr.
- 18. Venue is proper in this Court pursuant to 28 U.S.C. §§ 1391(b) and (c) and 1400(b).

## IV. THE PATENT-IN-SUIT (U.S. PATENT NO. 5,908,838)

- 19. The allegations of ¶¶ 1-18 are incorporated herein by reference.
- 20. Medicis is the owner of all right, title and interest in the '838 patent. The United States Patent and Trademark Office duly and legally issued the '838 patent on June 1, 1999, to Eugene H. Gans, which was assigned to Medicis. A true and correct copy of the '838 patent is attached as Exhibit A.
- 21. On May 8, 2006, the FDA approved Medicis's new drug application 50-808 for SOLODYN<sup>TM</sup> minocycline HCl extended release tablets in its 45mg, 90mg, and 135mg strengths under § 505(b) of the FFDCA, 21 U.S.C. § 355(b), for the treatment of acne. On July 23, 2009, the FDA approved Medicis's supplement to new drug application 50-808 for SOLODYN<sup>TM</sup> minocycline HCl extended release tablets in its 65mg and 115mg strengths under § 505(b) of the FFDCA, 21 U.S.C. § 355(b), for the treatment of acne.
- 22. The use of SOLODYN<sup>TM</sup> minocycline HCl extended release tablets is covered by the '838 patent, and Medicis has the right to enforce the '838 patent.

- 23. The FDA listed the '838 patent in the Orange Book on December 3, 2008 for SOLODYN™ in its 45mg, 90mg and 135mg strengths, and on August 14, 2009 for SOLODYN™ in its 65mg and 115mg strengths.
- 24. On information and belief, Defendants submitted the Barr ANDA Supplement to the FDA after the '838 patent was listed in the Orange Book.

#### V. COUNT FOR RELIEF (INFRINGEMENT OF THE '838 PATENT BY DEFENDANTS)

- 25. The allegations of ¶¶ 1-24 are incorporated herein by reference.
- 26. On information and belief, Barr filed the Barr ANDA Supplement under § 505(j) of the FFDCA to obtain approval to commercially manufacture, use, offer for sale and sell a generic version of SOLODYN™ minocycline HCl extended release tablets in its 65mg and 115mg strengths for the treatment of acne before the expiration of the '838 patent.
- 27. On or about November 21, 2009, Medicis received a letter ("Barr Notice Letter") dated November 20, 2009, from Teva stating that Barr had filed the Barr ANDA Supplement seeking approval to manufacture, use, offer for sale and sell a generic version of SOLODYN<sup>TM</sup> minocycline HCl extended release tablets in its 65mg and 115mg strengths for the treatment of acne before the expiration of the '838 patent. The letter notifies Medicis that the Barr ANDA Supplement was submitted with a Paragraph IV certification that the '838 patent purportedly is invalid. The Barr Notice Letter did not provide a "detailed statement of the factual and legal basis" for any claim of noninfringement of claims 3, 4, 12, and 13 of the '838 patent, as required under 21 U.S.C. § 355(j)(2)(B)(iv)(II).
- 28. On information and belief, Teva participated in, contributed to, aided, abetted, and/or induced Barr's submission of the Barr ANDA Supplement and its Paragraph JV allegations to the FDA.